

# **EXHIBIT 26**

NOV 16 '94 12:05 PM J-J CORP PR  
NOV 15 '94 04:45 PM J&J CFI TELETYPE

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P.01/02



## CANCER PREVENTION COALITION

NOV 14 1994

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520 NORTH MICHIGAN AVENUE - SUITE 410 CHICAGO, IL 60611 • 312-467-0600 • FAX 312-467-0599

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Director

November 10, 1994

Ralph Larson  
C.E.O.  
Johnson & Johnson, Inc.  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933

Dear Mr. Larson,

A wide range of scientific studies dating back to the 1960s shows conclusively that the frequent use of talcum powder in the genital area poses a serious risk of ovarian cancer.

Dr. Bernard Harlow, a leading ovarian cancer researcher from Harvard Medical School, published a comprehensive study in 1992 of the link between talc and ovarian cancer. The study found a threefold increase of ovarian cancer in women who used talc in the genital area as a daily habit. Dr. Harlow warns:

"...given the poor prognosis for ovarian cancer, any potentially harmful exposures should be avoided, particularly those with limited benefits. For this reason, we discourage the use of talc in genital hygiene, particularly as a daily habit."

Furthermore, the U.S. National Toxicology Program has recently confirmed that talc is carcinogenic.

This year alone, 14,000 women will die from ovarian cancer, giving it the fourth highest women's cancer death rate. Ovarian cancer is very difficult to detect and has a low survival rate. Researchers can attribute only 3% of all ovarian cancer cases to family history of the disease.

Plaintiff's Exhibit  
No.

P-18

Cancer prevention through reduction of carcinogens in air, water, food, consumer products, and the workplace.

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NOV 16 '94 12:05 FR J-J CORP PR

Women have the unarguable right to know of this information. The Cancer Prevention Coalition urges you to immediately withdraw your talc products from the market and substitute them with a safer alternative, such as cornstarch. At the very minimum, we urge Johnson & Johnson to label its talcum powder products with information about the ovarian cancer risk they pose.

Over the next several months, the Cancer Prevention Coalition will be implementing a consumer labeling initiative to inform shoppers of the presence of avoidable carcinogens in cosmetics and other consumer products and enable them to shop for alternatives. We would greatly welcome your joining us in this effort on behalf of your customers.

If you have any questions, you can reach the Cancer Prevention Coalition at the above address and phone number. Thank you for your cooperation.

Sincerely,



Samuel S. Epstein, M.D.  
Chair

NOV 15 '94 16:52

201 874 1123

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# **EXHIBIT 27**

JERSEY JOURNAL (CITY  
EDITION)  
JERSEY CITY, N.J.  
DAILY 65,000  
WEDNESDAY  
APR 17 1996

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## Women's health concerns prompt condom makers to stop using talc

By Marie McCullough  
Knight-Ridder Newspapers

Candace Sue Kasper believes "safe sex" should be as safe for women as for men.

So early this year, the Dallas skin pathologist began urging some would say badgering — condom-makers and the federal Food and Drug Administration to stop the little-known practice of coating condoms with talc.

Talc, a powder made from the rocklike mineral magnesium silicate, is an excellent dry lubricant, but can scar soft tissues inside the body, where it does not dissolve. In women, body powders containing talc have been linked to infertility and ovarian cancer.

Kasper's campaign apparently worked.

"We've requested U.S. manufacturers to cease using (talc) and, in fact, all have agreed not to use it in manufacturing condoms," FDA spokesman Arthur Whitmore said in December.

Concern about talc as an ovarian carcinogen goes back 50 years in the medical literature. By the 1970s, evidence was mounting that talc particles might migrate into a woman's fallopian tubes where they could cause scarring and irritation of the ovaries. Scientists believed in some cases that the scarring led to infertility or cancer.

Carter-Wallace, which makes Trojans and claims 60 percent of the American condom market, said in a statement that "to allay any possible concern," it has "discontinued the use of talc in its condom manufacturing process."

**'Why take the risk?'**

Kasper, 46, feels vindicated, but not victorious. She said an FDA official told her the agency has not been proven to be harmful — because cornstarch is a cheap, safe alternative.

"We'll probably never know for sure" that condom talc is unsafe, he said. "But why take the risk? Cornstarch does just fine and doesn't pose risks. I think it's prudent for manufacturers" to switch.

Indeed it is, said Ansell Inc. of Eatontown, N.J., which makes LifeStyle condoms and has about a quarter of the American condom market. Ansell switched from talc to cornstarch in January 1994.

"We knew surgical glove talc was a problem, so we figured there might be a problem with condoms," said Milt Hinsch, Ansell's vice president of technical affairs. "Whether it's rational or scientific, you just have to say, 'Let's not argue about it. Let's just do it.'"

In 1990, the FDA asked manufacturers to voluntarily stop putting talc on surgical gloves amid mounting scientific evidence that it caused adhesions in surgical patients. At the same time, the agency evaluated talc on condoms, but concluded the amount was insignificant and did not pose problems, said FDA spokeswoman Sharon Snider.

**Talc in breast tissue**

Kasper's concern about condoms arose after she and a colleague, Dallas plastic surgeon Preston Chandler, discovered talc in the hardened tissue surrounding breast implants that had been removed from women.

In a 1994 journal article, the two physicians speculated that the talc might have contributed to the hardening and that it came from surgical gloves. They also speculated that talc might play a role in the autoimmune symptoms that are the subject of numerous breast implant lawsuits.

Curious to see whether other products were dusted with talc, Kasper and Chandler bought condoms, pacifiers and baby-bottle nipples in 1994 at Dallas-area stores, then scrutinized them under a microscope. The nipples and pacifiers appeared clean, but all eight brands of American-made and foreign-made condoms had varying amounts of

talc, cornstarch and, in some cases, substances such as sand, silicone dioxide or club moss spores (an outmoded lubricant that also causes scarring in soft tissues).

Kasper and Chandler wrote to the condom manufacturers, several of which responded that they did not use talc in their production process. Carter-Wallace did not respond to them, Kasper said.

Only one manufacturer, Ansell, backed up its claim to be talc-free, Kasper said. She examined Ansell condoms made after January 1994 and found cornstarch, not talc.

She and Chandler also expressed their concern to the FDA, which thanked them for their information — but didn't say it would take any action.

"Largely, we've been ignored," said Kasper, who has a private pathology practice and is a staff physician at Baylor Medical Center. "Fortunately, my livelihood doesn't depend on this. I've done this on my own time and money."

**Journal spurred action**

What spurred the FDA to act was a letter to the editor from Kasper and Chandler, published in the March 15 Journal of the American Medical Association, warning about talc on condoms. The FDA's office of device evaluation wrote to four American condom makers, enclosing a copy of the JAMA letter.

"Please let us know if you are using talc in your condom manufacturing process," said the FDA's letter — which did not specifically say to stop using it.

The FDA's Snider said the FDA inspects condoms for holes, but not contaminants, so talc compliance is voluntary.

What's to stop condom-makers from returning to talc?

"Right at the moment, legally, nothing," Snider said.

Several manufacturers' spokesmen asserted they did not use talc.

David Mayer, president of the company that distributes Japanese-made Sagami condoms, said the product was lubricated with silicone oil.

"But there is no scientific evidence that talc on condoms does any harm," he said.

Carter-Wallace spokesman Steven Curtis would not say what lubricant the company had substituted for talc.

Neither would Leanne Hand, spokeswoman for London International U.S. Holdings Inc., which distributes Japanese-made condoms including Ramseys.

The company "did use talc until about 1989," she said.

Plaintiff's Exhibit  
No.

P-19

# **EXHIBIT 28**

'97-09-18 00:34 A.P.

P.1

ALFRED P. WEHNER, D.M.D., Sc.D., CAND. MED.  
 DIPLOMATE, ACADEMY OF TOXICOLOGICAL SCIENCES  
 312 SAINT STREET  
 RICHLAND, WASHINGTON 99352

9/17/97

Mr. Michael R. Chudkowski  
 Manager, Preclinical Toxicology  
 J&J Consumer Products, Inc.  
 Skillman, NJ 08558-9418

Dear Mike:

There is a German saying which translates as follows:

"A true friend is not he who beguiles you with flattery  
 but he who discloses to you your mistakes  
 before your enemies discover them."

In this spirit I would like to volunteer a critique of the three CTFA response statements which you faxed me on September 11. Some of the wording leaves CTFA wide open to counter-attack. The most harmless response statement of the three is the one dated July 1, 1992. It does not give the names of the authors and the title of the paper to which the response is being made. More important, I believe that different and/or additional more powerful statements along the lines of my critique faxed to Jerry McEwen, as far as applicable to the situation in 1992, would have put CTFA in a more advantageous tactical position. Several investigators have independently reported talc particles in ovarian tissue. Simply citing the Battelle study and stating that it "demonstrated that talc does not translate (sic!) through the cervix to the uterine cavity and beyond" does not address the problem, does not refute these findings, and therefore does not serve CTFA's best interest. All in all, in my opinion an inept response.

The problem with the response statement dated July 8, 1992, is more serious. The last sentence in the second paragraph states: "Finally, human studies on talc and cancer in industrial settings have shown that industrial exposure to talc, both by skin contact and inhalation, even at levels thousands of times higher than lifetime consumer exposure, presents no significant risk." This statement is outright false. All an Epstein, a Kennedy, or one of their aides knowledgeable in matters talc, would have to do at a hearing (or any occasion, at that) to demolish the credibility of the talc industry is to refer to the studies by Kleinfeld et al, Thomas, and Thomas and Stewart!

Referring in a 1992 statement to a 1977 editorial in defense of one's position is not a very persuasive argument. Much can happen in 15 years.

509/375-0873 Fax 509/375-5693

Plaintiff's Exhibit  
 No.

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'97-09-18 00:35 A.P.

P.2

Here, too, I believe that more powerful and better defensible arguments could and should have been made on behalf of the industry.

The response statement dated November 17, 1994, is just as bad. The second sentence in the third paragraph reads: "The workshop concluded that, although some of these studies suggested a weak association might exist, when taken together the results of the studies are insufficient to demonstrate any real association." This statement is also inaccurate, to phrase it euphemistically. At that time there had been about 9 studies (more by now) published in the open literature that did show a statistically significant association between hygienic talc use and ovarian cancer. Anybody who denies this risks that the talc industry will be perceived by the public like it perceives the cigarette industry: denying the obvious in the face of all evidence to the contrary. This would be a particularly tragic misperception in view of the fact that the industry does have powerful, valid arguments to support its position.

The workshop did not conclude that "the results of the studies are insufficient to demonstrate any real association." As pointed out above, a "real" statistically significant association has been undeniably established independently by several investigators, which without doubt will be readily attested to by a number of reputable scientists/clinicians, including Bernard Harlow, Debra Novotny, Candace Sue Kasper, Debra Heller, and others. What the workshop panel did conclude was that (1) the results of the studies were ambiguous, inconsistent, contradictory and therefore inconclusive, (2) therefore hygienic use of cosmetic talc does not present a risk to the consumer. So why not use these powerful and irrefutable arguments (plus some of those along the lines of my fax to Rich) instead of questionable mush that leaves one vulnerable to counterattack? The following sentence states: "In addition there is no basis to conclude that talc is capable of migrating to the ovaries...". I submit that several reports, independently describing talc particles in/on ovarian tissue, along with other suggestive evidence (questionable as some of it might be) does provide a basis for just such a conclusion. My point is that such a complex and vexing issue cannot be credibly dismissed with one sweeping statement without any documenting references.

Mike, I realize that CTFA is not J&J. However, I believe that a defeat or embarrassment of CTFA also negatively affects J&J to some extent. As a consultant on a retainer I feel obligated to proactively act in the best interest of my client at all times, not only when I am approached with a specific assignment. This consideration alone motivated me to spend the time to bring my thoughts on this matter to your attention. I trust that in the process I did not step on anybody's toes.

Best regards

*AL*



# **EXHIBIT 29**

## 6. Evaluation and Rationale

### 6.1 Cancer in humans

There is *inadequate evidence* in humans for the carcinogenicity of inhaled talc not containing asbestos or asbestiform fibres.

There is *limited evidence* in humans for the carcinogenicity of perineal use of talc-based body powder.

### 6.2 Cancer in experimental animals

There is *limited evidence* in experimental animals for the carcinogenicity of talc not containing asbestos or asbestiform fibres.

### 6.3 Overall evaluation

Perineal use of talc-based body powder is *possibly carcinogenic to humans* (Group 2B).

Inhaled talc not containing asbestos or asbestiform fibres is *not classifiable as to its carcinogenicity* (Group 3).

### 6.4 Rationale

In making this evaluation the Working Group considered the human and animal evidence as well as evidence regarding the potential mechanisms through which talc might cause cancer in humans.

The Working Group found little or inconsistent evidence of an increased risk for cancer in the studies of workers occupationally exposed to talc. The studies of talc miners and millers were considered to provide the best source of evidence, but no consistent pattern was seen. One study observed an excess risk for lung cancer among miners, but confounding from exposure to other carcinogens made it difficult to attribute this to talc and no excess risk was seen in millers. Other studies also found no increased cancer risk or no higher risk with increasing cumulative exposure. Overall, these results led the Working Group to conclude that there was *inadequate evidence* from epidemiological studies to assess whether inhaled talc not containing asbestos or asbestiform fibres causes cancer in humans.

For perineal use of talc-based body powder, many case-control studies of ovarian cancer found a modest, but unusually consistent, excess in risk, although the impact of bias and potential confounding could not be ruled out. In addition, the evidence regarding exposure-response was inconsistent and the one cohort study did not provide support for an association between talc use and ovarian cancer. Concern was also expressed that



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exposure was defined in a variety of ways and that some substances called talc may have contained quartz and other potentially carcinogenic materials. A small number of Working Group members considered the evidence to be inadequate. Despite these reservations, the Working Group concluded that the epidemiological studies taken together provide *limited evidence* of an association between perinatal use of talc-based body powder and an increased risk for ovarian cancer.

In one study of rats that inhaled talc, an excess incidence of malignant lung tumours was seen in females. The same study observed an excess incidence of pheochromocytomas in the adrenal medulla in both sexes, but the Working Group was divided as to whether these rare tumours could be attributed to exposure to talc. Other studies in rats and mice using different routes of administration did not find an excess of cancer, and two studies in rats were considered to be inadequate for evaluation. Based on the one positive study, the Working Group found that there was *limited evidence* of carcinogenicity of inhaled talc in experimental animals. There was no agreement within the Working Group as to whether the evidence on pheochromocytomas should be taken into account in the evaluation of animal data.

JNJ 000381976

# **EXHIBIT 30**

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**From:** Hubbard, Sue (RTM)  
**Sent:** Friday, July 7, 2006 07:40:33 AM  
**To:** Glenn, Robert[RGlenn@crowell.com]  
**CC:** Harrass, Michael (RTM)  
**Subject:** ACGIH

Bob,

On ACGIH, Mike Harrass is leading the team on ACGIH and can bring you up to date

Sue

*Dr Sue Hubbard  
Chief Toxicologist  
Rio Tinto Minerals  
Tel: +44 1483 242055  
Fax: +44 1483 242155 or 01244 303225  
Mob: +44 7802813302  
Email: sue.hubbard@borax.com  
Website: www.borax.com  
Telephone 01483 242000 Fax 01483 242001*

*Effective 1<sup>st</sup> February 2006, Borax is combining its management with two sister companies, namely Luzenac, the world leader in talc and Dampier Salt, the premier exporter of solar salt, to form a new organisation called **Rio Tinto Minerals**. The transition will take place progressively throughout 2006 for full implementation on 1<sup>st</sup> January 2007.*

*Registered Office : Borax Europe Limited 1A Guildford Business Park, Guildford, GU2 8XG. Registered In England No 36374*

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-----Original Message-----

**From:** Glenn, Robert [mailto:RGlenn@crowell.com]  
**Sent:** 30 June 2006 14:02  
**To:** Hubbard, Sue (RTM)  
**Subject:** RE: Publication Update

What is your reaction to ACGIH moving forward with development of a documentation for talc? How are you coming with progress on your notes re our June 13 Meeting? Have Great 4th of July! Sorry, you chaps don't celebrate that one - do you?

Kind regards,

Bob

---

**From:** Hubbard, Sue (RTM) [mailto:Sue.Hubbard@borax.com]  
**Sent:** Wednesday, June 28, 2006 5:38 AM  
**To:** Glenn, Robert; Argust, Peter (RTM); TURNER, Eric (LG CIT); Godell, Ralph (LNA); Bernard, Craig (USBORAX); Cutler, Kent (LNA); Keener, Mike (LNA); Yordan, Jorge (LNA); Brown, Judy P. (USBORAX); REFREGIER, Michele (LEU); Harrass, Michael (USBORAX); William G. Kelly, Jr.; Zazenski, Rich (LNA); Hall, Ridgway; Hall, Ridgway  
**Cc:** Metaresearch@hotmail.com; JMuscato@PSU.edu; Hall, Ridgway  
**Subject:** RE: Publication Update

Well done - look forward to getting reprints

Sue

*Dr Sue Hubbard  
Chief Toxicologist  
Rio Tinto Minerals  
Tel: +44 1483 242055  
Fax: +44 1483 242155 or 01244 303225*

Plaintiff's Exhibit  
No.

P-78

Mob: +44 7802813302

Email: sue.hubbard@borax.com

Website: www.borax.com

Telephone 01483 242000 Fax 01483 242001

*Effective 1<sup>st</sup> February 2006, Borax is combining its management with two sister companies, namely Luzenac, the world leader in talc and Dampier Salt, the premier exporter of solar salt, to form a new organisation called **Rio Tinto Minerals**. The transition will take place progressively throughout 2006 for full implementation on 1<sup>st</sup> January 2007.*

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-----Original Message-----

**From:** Glenn, Robert [mailto:RGlenn@crowell.com]

**Sent:** 27 June 2006 17:46

**To:** Argust, Peter (RTM); TURNER, Eric (RTM); Hubbard, Sue (RTM); Godell, Ralph (RTM); Bernard, Craig (RTM); Cutler, Kent (RTM); Keener, Mike (RTM); Yordan, Jorge (RTM); Brown, Judy P. (RTM); REFREGIER, Michele (LEU); Harrass, Michael (RTM); William G. Kelly, Jr.; Glenn, Robert; Zazenski, Rich (RTM); Hall, Ridgway; Hall, Ridgway

**Cc:** Metaresearch@hotmail.com; JMuscato@PSU.edu; Hall, Ridgway

**Subject:** Publication Update

Ladies and Gentlemen,

I received some fantastic news from Drs. Huncharek and Muscat regarding the manuscripts regarding talc and ovarian cancer which they submitted to the medical literature. First, the manuscript on the meta-analytic study of diaphragm storage in talc and a possible relationship with ovarian cancer has been accepted and will be published in the European Journal of Cancer Prevention. The editor, Carlo LaVecchia, advised Michael by e-mail. Dr. LaVecchia is a prominent figure in cancer prevention and this is an ideal journal in which to have this study appear. Secondly, the review manuscript on the relationship between perineal talc dusting and ovarian cancer has been provisionally accepted and will be published in the Journal of Clinical Epidemiology after minor formatting revisions are made. Another well-respected scientific journal for publication of their manuscript. I know you all join me in commending Michael and Josh for their first-rate study on the talc-diaphragm meta-analysis and their splendid review article on the literature regarding talc and ovarian cancer. We will apprise you as we learn of publication dates for these articles.

Again, thanks Mike and Josh and congratulations!

Kind regards to all,

# **EXHIBIT 31**



**From:** Hubbard, Sue (RTM)  
**Sent:** Friday, March 31, 2006 02:07:50 AM  
**To:** Harrass, Michael (USBORAX); Bernard, Craig (USBORAX); Branch, Tracy (USBORAX); Shettle, Keith (RTM); Hoadley, Lara (RTM); Rickards, Helen (RTM)  
**Subject:** FW: Lancet publication of IARC Summaries - Out this morning  
**Attachments:** Lancet Oncology.doc

[More on talc](#)

Sue

Dr Sue Hubbard  
 Regulatory Toxicology Manager  
 Rio Tinto Minerals  
 Tel: +44 1483 242055  
 Fax: +44 1483 242155 or 01244 303225  
 Mob: +44 7802813302  
 Email: sue.hubbard@borax.com  
 Website: www.borax.com  
 Telephone 01483 242000 Fax 01483 242001

*Effective 1<sup>st</sup> February 2006, Borax is combining its management with two sister companies, namely Luzenac, the world leader in talc and Dampier Salt, the premier exporter of solar salt, to form a new organisation called **Rio Tinto Minerals**. The transition will take place progressively throughout 2006 for full implementation on 1<sup>st</sup> January 2007.*

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-----Original Message-----

**From:** Zazenski, Rich (LNA)  
**Sent:** 28 March 2006 20:09  
**To:** Goldberg, Gary (RTM); Parr, Adam (RTM); Keefe, Susan (RTM); Argust, Peter (RTM); JONES, Laura (LEU); Stockman, Mike (USBORAX); Robison, Chris (RTM); Goldsworthy, Denise (DSL); Brown, Judy P. (USBORAX); Sperring, Keith (RTM); TURNER, Eric (RTM); Argust, Peter (RTM); Saperstein, Steve (RTM); Olsen, Jeff (RTM); Hubbard, Sue (RTM)

**Subject:** Lancet publication of IARC Summaries - Out this morning  
**Importance:** High

To all - Peter asked that I summarize for you the latest developments on the IARC review of talc. This morning, the journal *Lancet Oncology* published a summary of the IARC classifications of Talc, TiO<sub>2</sub>, and Carbon Black for IARC Monograph 93. The summary is surprising brief and low key. While it is too early to tell if the release of the summary will garner widespread press coverage, we are cautiously optimistic right now that the release may fly under the radar screen of major news organizations. When you read the summary of the talc/ovarian cancer issue, you'll see that there remains many unaddressed questions.

I've spoken with J&J's Steve Mann and he is also somewhat optimistic - as is their lead attorney John O'Shaughnessy. We'll just have to wait and see what develops in the next few days (Suzi - I forwarded a copy of the Lancet piece to Iris Grossman at J&J - although I haven't heard anything back from her. You might want to give her a call).

Depending on what happens in the coming days and weeks, we'll need to maintain flexibility in our strategy in dealing with the aftermath. For instance, we (J&J with assistance from Luzenac) had plans for Dr. Michael Hunkarek to write a letter to the editor of Lancet taking issue with how the IARC Working Group dealt with the epidemiology studies on talc. As of right now, it looks like we are going to hold off on this due to the many ambiguities in the summary.

We will keep you apprised of any late breaking developments - but so far, so good.

Rich

Plaintiff's Exhibit  
No.

P-92

exhibitstick.com



# **EXHIBIT 32**

June 30, 2005

William G. Kelly

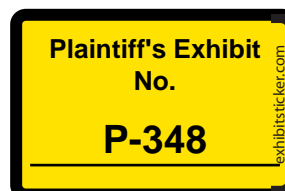
Re: Talc and Ovarian Carcinogenesis

Dear Bill:

Per your request, I have undertaken and completed a systematic discovery of medical scientific experts on the epithelial ovarian carcinogenesis. The objectives of this task were a) to identify such individuals from several disciplines who could be responsible for reviewing the body of scientific literature on talc and ovarian carcinogenesis in order to arrive at an independent and objective conclusion as to whether talc is a likely or definite ovarian carcinogen and b) to form a "priority list" within each discipline based on level of expertise and reputation, research interest and likelihood of objectivity.

Experts were sought in the disciplines of Epidemiology (preferably with background in Biostatistics), Molecular & Cell Biology of Carcinogenesis (emphasizing in vivo models), Pathology, Gynecologic Oncology and General Gynecology. Since all gynecologic oncologists are also board certified in general gynecology and consolidation of manpower is an important consideration, general gynecologists without expertise in gynecologic oncology or the other relevant fields, were not sought.

In addition to personal knowledge of such experts, The National Center for Biotechnology Information (<http://www.ncbi.nlm.nih.gov/>) was used to perform a comprehensive search. Complete and selected bibliographies were then reviewed to identify individuals with appropriate expertise. Some individuals were also identified from the Committee on Cancer Prevention and Control of the Gynecologic Oncology Group (<http://www.gog.org/>) as this important national cooperative group committee has had particular interest in mechanisms of ovarian carcinogenesis and primary prevention. Of the more than two hundred individuals initially identified and screened, a final list of 21 was generated. Some of these thought investigators/thought leaders have expertise in more than one discipline. I have provided tables for each discipline with a rank order and rationale for the rank order below.



## Epidemiology

| Rank | Last      | First   | Degree     | Title   | Institution                        | URL   |
|------|-----------|---------|------------|---|------------------------------------|---|
| 1    | Brinton   | Louise  | PhD        | Senior Investigator, Chief -<br>Hormonal and Reproductive<br>Epidemiology Branch<br>Unit Chief, Department of<br>Obstetrics, Gynecology &<br>Reproductive Biology | NCI                                | <a href="http://dceg.cancer.gov/people/BrintonLouise.htm">http://dceg.cancer.gov/people/BrintonLouise.htm</a> |
| 2    | Cramer    | Daniel  | MD<br>MD,  | Professor, Epidemiology   | Brigham &<br>Women's Hospital      | <a href="http://www.brighamandwomens.org/WRHRprog">http://www.brighamandwomens.org/WRHRprog</a>               |
| 3    | Risch     | Harvey  | PhD        | Professor, Epidemiology   | Yale University                    | <a href="..\..\PDF\Personal\Risch H Biblio.pdf">..\..\PDF\Personal\Risch H Biblio.pdf</a>                     |
| 4    | Harlow    | Bernard | PhD<br>MD, | Professor, Epidemiology<br>Professor of Medicine,   | Harvard School of<br>Public Health | <a href="#">Bernard Harlow, Associate Professor in the Depa</a>   |
| 5    | Colditz   | Graham  | PhD        | Epidemiologist<br>Associate Professor of  | Harvard Medical<br>School          | <a href="#">Channing Laboratory - Graham A. Colditz, MD,</a>  |
| 6    | Hankinson | Susan   | ScD        | Medicine, Epidemiologist  | Harvard Medical<br>School          | <a href="#">Channing Laboratory - Susan E. Hankinson, ScD</a>   |
| 7    | Rodriguez | Carmen  | MD,        | Senior Epidemiologist   | American Cancer<br>Society         |   |
| 8    | Daly      | Mary    | PhD        | Senior Member, Population<br>Science Division   | Fox Chase Cancer<br>Center         | <a href="#">Fox Chase Cancer Center: Mary B. Daly, M.D., I</a>  |

## Rationale for Rank Order (first three candidates):

Louise Brinton is a highly regarded epidemiologist with an important administrative position within NCI, who is highly prolific in epidemiology in general and in the epidemiology of ovarian cancer in particular. She has not participated in any studies related to talc exposure that I can tell, so would likely remain unbiased in this regard. She is also a member of the GOG CPC.

Daniel Cramer is an epidemiologist who I believe received his medical subspecialty training in Obstetrics & Gynecology. He is a highly regarded ovarian cancer epidemiologist with a strong publication list in this area. He was a key investigator in the prospective cohort study of talc exposure and ovarian cancer development. This is the most scientifically reputable epidemiologic study in this area. A key factor in the selection of Dr. Cramer to the short list is his combined experience in gynecology and ovarian cancer epidemiology.

Harvey Risch is an MD, PhD, Professor of Epidemiology at Yale and a world renowned ovarian cancer epidemiologist. Based on his selected publication list, he is also likely to remain unbiased. I have had personal contact with Dr. Risch.

## Molecular &amp; Cell Biology of Carcinogenesis

| Rank | Last      | First  | Degree  | Title  | Institution  | City         | State | URL                                 |
|------|-----------|--------|---------|--|--|--------------|-------|-------------------------------------|
| 1    | Auersperg | Nelly  | MD, PhD | Professor of Obstetrics & Gynecology           | University of British Columbia                         | Vancouver    |       | <a href="#">Interdisciplinary V</a> |
| 2    | Godwin    | Andrew | PhD     | Member, Medical Science Division               | Fox Chase Cancer Center                                | Philadelphia | PA    | <a href="#">Fox Chase Canc</a>      |
| 3    | Hamilton  | Thomas | PhD     | Senior Member, Medical Division                | Fox Chase Cancer Center                                | Philadelphia | PA    | <a href="#">Fox Chase Canc</a>      |
| 4    | Bell      | Debra  | MD      | Associate Professor of Pathology               | Harvard Medical School<br>M.D. Anderson Cancer Center  | Boston       | MA    | <a href="#">Pathology Servic</a>    |
| 5    | Bast      | Robert | MD      | Professor<br>Senior Member, Population Science | M.D. Anderson Cancer Center                            | Houston      | TX    | <a href="#">Robert C. Bast, J</a>   |
| 6    | Testa     | Joseph | PhD     | Division<br>Chairman, Department of Molecular  | Fox Chase Cancer Center<br>M.D. Anderson Cancer Center | Philadelphia | PA    | <a href="#">Fox Chase Canc</a>      |
| 7    | Mills     | Gordon | MD, PhD | Therapeutics                                   |  | Houston      | TX    | <a href="#">M. D. Anderson C</a>    |

## Rationale for Rank Order (first three candidates):

Nelly Auersperg is one of the most accomplished and well renowned reproductive scientists in the area of ovarian carcinogenesis and the biology of the surface ovarian epithelium. She is number one, hands down. She is also trained in Obstetrics & Gynecology so functionally covers two categories..

Andrew Godwin is the most accomplished current basic scientist in the area of ovarian carcinogenesis. He is a close colleague and disciple of Thomas Hamilton. His work is truly cutting edge.

Thomas Hamilton is a pioneer in the biology of ovarian carcinogenesis and has experience in several in vivo model systems (similar to Dr. Godwin). He is also one of the only scientist to publish on the basic scientific relationship between talc and ovarian cancer.

## Pathology

| Rank | Last    | First    | Degree | Title  | Institution                    | City      | State | URL   |
|------|---------|----------|--------|--|--------------------------------|-----------|-------|---|
| 1    | Kurman  | Robert   | MD     | Professor of Pathology & Obstetrics/Gynecology | Johns Hopkins                  | Baltimore | MD    | <a href="#">Gynecologic Pathology</a>       |
| 2    | Bell    | Debra    | MD     | Associate Professor of Pathology               | Harvard Medical School         | Boston    | MA    | <a href="#">Pathology Service at MGH</a>    |
| 3    | Cho     | Kathleen | MD     | Professor of Pathology & Internal Medicine     | University of Michigan         | Ann Arbor | MI    | <a href="#">University of Michigan - Dr</a> |
| 4    | Orsulic | Sandra   | PhD    | Assistant Professor, Molecular Pathology       | Massachusetts General Hospital | Boston    | MA    | <a href="#">Pathology Service at MGH</a>    |

## Rationale for Rank Order:

Robert Kurman is a double boarded pathologists and obstetrician-gynecologist who is an icon of ovarian cancer pathology. His CV speaks for itself.

Debra Bell is a molecular pathologist with expertise on carcinogenesis of epithelial ovarian tumors. She is Associate Professor in the Department of Pathology at Harvard Medical School and trained under Dr. Scully, the father of ovarian pathology.

Dr. Cho is a Professor of both Pathology and Internal Medicine with a large body of experience in ovarian cancer pathology. She has several basic scientific interests including the molecular classification of ovarian carcinomas. I know Dr. Cho personally and she is not only well respected, but well spoken.

Dr. Orsulic is also a molecular pathologist from a good institution, with a more limited C.V. than Dr. Bell, but with important expertise in mouse models of ovarian carcinogenesis.

## Gynecologic Oncology

| Rank | Last     | First  | Degree      | Title  | Institution                      | City   | State | URL   |
|------|----------|--------|-------------|--|----------------------------------|--------|-------|---|
| 1    | Berchuck | Andrew | MD          | Professor of Obstetrics & Gynecology<br>Associate Professor,             | Duke University                  | Durham | NC    | <a href="#">Duke University IGSP Site -- Ar</a> |
| 2    | Brewer   | Molly  | MD, DVM, MS | Obstetrics & Gynecology,<br>Gynecologic Oncology<br>Associate Professor, | University of Arizona            | Tuscon | AZ    | <a href="#">University of Arizona, Departme</a> |
| 3    | Burger   | Robert | MD          | Obstetrics & Gynecology,<br>Gynecologic Oncology                         | University of California, Irvine | Orange | CA    | <a href="#">ROBERT ALLEN BURGER, M</a>          |

Any of these would be excellent, though I am obviously biased in including myself in this list.

Andrew Berchuck is probably the most highly regarded combination of gynecologic oncologist and basic ovarian cancer researcher. Although most of his work has dealt with ovarian carcinogenesis as it relates to molecular genetics, he is a key thought leader in the general subject of epithelial ovarian cancer pathogenesis. He is also president-elect for the Society of Gynecologic Oncologists and a personal colleague. He is not only brilliant and analytical, but extremely classy and well spoken individual.

Molly Brewer is a gynecologic oncologist at U of A with a focused research interest in precursors of ovarian carcinoma development. She is highly involved in primary prevention studies.

Robert Burger is a gynecologic oncologist with a research program dedicated to ovarian cancer pathogenesis and therapeutics. He is a member of several important committees in the Gynecologic Oncology Group, including the Ovarian Cancer Committee, the Committee on Experimental Medicine, and the Developmental Therapeutics Committee. He has an academic interest in ovarian carcinogenesis and prevention, including multiple invited lectures on this subject and organizing and directing a symposium on this subject at his local NCI comprehensive cancer center.

# **EXHIBIT 33**

To: IMA-NA Talc Section

From: Mark Ellis, President

Re: Marshalling Talc Industry Resources for IARC Monograph 93

Date: August 15, 2005

### Background

During its teleconference on August 11, 2005, the Industrial Minerals Association – North America (IMA-NA) Talc Section, in collaboration with the Industrial Minerals Association – Europe (IMA-EU) and the Cosmetic, Toiletry, and Fragrance Association (CTFA), discussed how the talc industry should mobilize its resources to inform the International Agency for Research on Cancer (IARC) Working Group deliberating the carcinogenicity of non-asbestiform talc. The Talc Section requested IMA-NA staff to summarize the subject of their discussions in a short paper, outlining the pros and cons of each activity, and offering an estimate of prospective costs associated with each activity. IMA-NA Talc Section members, and IMA-EU and CTFA staff, agreed to forward the options paper to their principals to determine which activities were of most interest and highest priority, which activities should be funded, and how to the cost of those activities should be allocated. The IMA-NA Talc Section, and collaborating organizations, will discuss their priorities and the commitment of resources during a teleconference scheduled for Thursday, August 18, at 9:30 a.m. (EDST). The consensus of the group was that time was of the essence in resolving a course of action so that necessary steps could proceed apace.

### Activities

The discussion revolved around four identified activities: 1) formation of a talc industry task force to assemble documentation and arguments to support talc during the deliberations of the IARC Working Group; 2) collaboration with the International Carbon Black Producers Association (ICBPA) and the American Chemistry Council's Titanium Dioxide Panel (ACC TiO<sub>2</sub> Panel), whose primary products also are the subject of Monograph 93; 3) retention of one or more industry observers to represent the talc industry at the February 2006 meeting of the Working Group in Lyon, France; and 4) initiation of scientific research studies that reasonably could be completed and published, or accepted for publication, in peer-reviewed journals before the February 2006 meeting of the Working Group. Each of these activities is summarized below.

### Formation of a Talc Industry Task Force

During its teleconference meeting on July 15, 2005, the IMA-NA Talc Section, and collaborating organizations, agreed to form a talc industry task force to assemble documentation and arguments to support talc during the deliberations of the IARC Working Group. The following individuals were identified as task force participants: Eric Turner (Luzenac); Rich Zazenski (Luzenac); Mike Larson (Minerals Technologies) Ed de Beus (Mondo Minerals); Linda Loretz (CTFA); Michelle Wyart-Remy (IMA-EU) and Mark Ellis (IMA-NA). The first activity of the





task force is to assemble the pertinent scientific literature expected to be considered by the Working Group. The task force is composed of member volunteers and association staff, affording a pool of talc industry expertise utilizing sweat-equity contributions. Staff time and travel are the likely costs associated with this activity.

#### Talc Industry Collaboration with the ICBPA and ACC TiO2 Panel

For the past several months, IMA-NA staff and company representatives have been holding regular teleconferences with representatives of the ICBPA and ACC TiO2 Panel. Each of the interest groups has provided updates on scientists they were encouraging to self-nominate as potential Working Group members or, alternatively, as Invited Specialists. The collaborators also have discussed whom they might nominate as industry observers and how the organizations representing the three substances under review in Monograph 93 might best coordinate their activities with common purpose. The collaborators have agreed to hold a meeting in Arlington, VA, on September 13, 2005, to brief each other on the issues underlying their primary products and to determine areas of commonality and divergence relative to the Working Group. Staff time and travel costs are expected to be minimal. However, Luzenac has underwritten the participation of Bob Glenn in teleconferences to date, and the cost of his past and continued participation in this activity cannot be viewed as minimal. The collaboration has the potential for future cost savings by pooling activities of the organizations that would otherwise be required independently, such as maintaining a “war room” in Lyon, France, during the meeting of the Working Group.

#### Industry Observers to Represent the Talc Industry

Under IARC procedures industries with substances under review by IARC are invited to nominate individuals for credentialing as Industry Observers at the Working Group meeting. Unlike Working Group members, Industry Observers have a limited role and no vote in the deliberations of the Working Group. IARC has defined the scope of activities for Industry Observers (see attached *IARC Observer Guidelines*), but they typically have played a significant role in their interactions and contributions to the deliberations of the Working Group. Their acceptance often is a factor of the expertise, utility and congeniality they bring to the Working Group’s deliberations. Unlike Working Group members, or Invited Specialists, IARC provides no financial support for industry observers. Nominees are expected to be self-sustaining (financially supported by outside sources). During last week’s teleconference Talc Section members determined that it was premature to identify specific individuals to nominate to serve as Industry Observers. It was agreed that the talc industry should examine the make-up of the Working Group, as determined by IARC, and evaluate whether any of the scientists the talc industry was encouraging to self-nominate as potential Working Group members or, alternatively, as Invited Specialists were not selected and might make suitable Industry Representatives. Two types of professional expertise were discussed: 1) expertise in evaluating lung overload as a potential mechanism of action in lung cancer, and 2) expertise in evaluating associations between talc exposure and ovarian cancer. Costs associated with retaining an Industry Observer typically would include the cost of their professional consultation (prior to, during, and following the Working Group meeting) and associated travel expenses. It is estimated that the cost of retaining and underwriting an Industry Observer would be \$50,000.

Two Industry Observers would cost on the order of \$100,000. Retention of an Industry Observer(s) to represent the talc industry at the Working Group meeting is regarded as essential to having the ability to monitor, and potentially influence, the outcome of the meeting.

#### Initiation of Scientific Research Studies

During last week's teleconference Talc Section members considered two proposals for scientific research studies that reasonably could be completed and published, or accepted for publication, in peer-reviewed journals before the February 2006 meeting of the Working Group. Studies completed for consideration by the Working Group also would have utility before the U.S. National Toxicology Program (NTP) should it decide to pursue listing talc in the 12<sup>th</sup> *Report on Carcinogens*.

RTI Health Solutions (RTI-HS) proposes to update a report entitled *Assessing the Epidemiologic Literature on the Carcinogenicity of Talc*. This report, written in 2000 by Rothman, Pastides, Muscat and Samet, included a meta-analysis (quantitative literature review) of about 20 epidemiologic studies, as well as a meta-regression that examined dose-response trends based on duration and intensity. The original report is viewed as having been instrumental in the decision by the U.S. National Toxicology Program to defer listing talc in the 10<sup>th</sup> *Report on Carcinogens*. The RTI-HS proposes to bring the literature review up to date and repeat the meta-analysis and meta-regression analyses to evaluate the extent to which recently published studies may have affected the weight of evidence. The study offers the prospect of bringing the most up-to-date information on the critical topic of human epidemiology before the Working Group. The research team is authoritative and highly regarded. However, the consensus of Talc Section members is that the study is overpriced at \$100,000. An effort to reduce the projected cost of the study would be undertaken should the Talc Section be interested in underwriting this research study. The original report by Rothman, *et al.*, and the proposal from RTI-HS are attached (see attached *Rothman – 10<sup>th</sup> ROC Comments* and *C0205.185 7-5-05*).

Dr. Brooke Mossman, affiliated with the University of Vermont College of Medicine, proposes to compare gene profiling by non-asbestiform talc to that of crocidolite asbestos in human mesothelial and ovarian epithelial cells. Little is known about the cellular and molecular effects of talc on cells. Gene profiling studies have been done on chrysotile asbestos. In contrast to titanium dioxide (a non-pathogenic, control dust), chrysotile induces a number of genes linked to inflammation, fibrogenesis and loss of cell control. Gene profiling increasingly is being used in evaluating the carcinogenic potential of substances. While human epidemiology is likely to be determinative in the Working Group evaluation of talc, studies that demonstrate the absence of a plausible mechanism of action will cast doubt on causal associations between exposure to talc and cancer. Dr. Mossman is a recognized expert in cellular pathology. The projected cost of the study is \$75,000. The proposal from Dr. Mossman is attached (see attached *Talc vs Asbestos 6-30-05*).

#### Cost Allocation Options

IMA-NA has no institutional formula for allocating the cost of activities pursued by its member sections. Activities pursued by a section, beyond sweat equity and reasonable staff time, are

expected to be self-funded. Thus, it is imperative for Talc Section member companies to determine which activities are of most interest and highest priority, which activities should be funded, and how the cost of those activities should be allocated. Discussion in last week's teleconference suggested that market share might serve as a reasonable basis for allocating the cost of any activities pursued, but antitrust considerations precluded any attempt to discern such a formula under the auspices of IMA-NA. However, IMA-NA staff offered to consult the U.S. Geological Survey (USGS) commodity report for talc to determine if some external source had attempted to make such a determination. However, upon investigation, we learned that USGS has not formally published the market shares of domestic talc producers.

IMA-EU and CTFA, and/or their members, also may be willing to underwrite the cost of any activities determined worthy of pursuit. IMA-EU and CTFA staff have agreed to pursue interest in this regard within their organizations.

#### Closing Observations

Funding a talc industry initiative to evaluate the carcinogenicity of talc may be a case of: "You can pay me now, or you can pay me later." IARC is viewed around the globe as an authoritative body when it comes to determining the carcinogenicity of chemical substances. An affirmative finding assuredly will follow the product in the future and likely will result in producers of that product being subject to product liability and occupational tort liability actions. The cost of defending these lawsuits, even meritless ones, can be expected to be substantial. An investment at this time to ensure that the existing scientific literature on talc is evaluated appropriately by the Working Group, perhaps resulting in a determination of no, or limited, carcinogenic association could be viewed as a prudent business decision in the long run.

Should you have any questions regarding the contents of this memorandum, please do not hesitate to contact me.

Mark G. Ellis  
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Industrial Minerals Association - North America  
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# **EXHIBIT 34**



# MATERIAL DATA SAFETY SHEET TALC

Plaintiff's Exhibit  
No.

P-215

## Section 1. Product and Company Identification

### Product Names

|                           |                                    |                                |
|---------------------------|------------------------------------|--------------------------------|
| <b>Grade 25 USP</b>       | <b>Imperial 200 USP</b>            | <b>Imperial 400Y USP</b>       |
| <b>Imperial 250 USP</b>   | <b>Imperial 400 USP</b>            | <b>Imperial 500 USP</b>        |
| <b>1885L USP/BC</b>       | <b>Imperial 1889L USP/BP/EP/BC</b> | <b>Imperial 1890 USP/BC</b>    |
| <b>1892L USP/BP/EP/BC</b> | <b>Olympic H USP</b>               | <b>Imperial Olympic HY USP</b> |
| <b>Suprafino HP USP</b>   | <b>Supra H USP</b>                 | <b>Supreme H USP</b>           |
| <b>Imperial 180 USP</b>   |                                    |                                |

**Synonyms** Talcum powder, Soapstone, Steatite

**Chemical Name** Talc ; Hydrous magnesium silicate **CAS#** 14807-96-6 **Chemical Family** Phyllosilicates

**Manufacturer** Luzenac America, Inc.  
8051 E. Maplewood Avenue, Bldg 4  
Greenwood Village, CO 80111  
Toll-free +1-800-325-0299 (General Information)

**Emergency Health Information (24 hrs)**  
303-623-5716

## Section 2. Composition/Information on Ingredients

| Substance | CAS#       | % by Weight | TLV - TWA                                       |
|-----------|------------|-------------|---|
| Talc      | 14807-96-6 | 98-100      | 2 mg/m <sup>3</sup> respirable fraction (ACGIH) |
| Dolomite  | 16389-88-1 | 0-2         | Use Talc TLV for total exposure measurements    |

## Section 3. Health Hazards Identification and Emergency Overview

**Emergency Overview** Under normal conditions of use, this product is not expected to create any unusual emergency hazards. This product is **NOT** flammable, **NOT** reactive, **NOT** explosive, has **NO** flash point, and poses **NO** special hazards in the presence of fire.

### Potential Health Effects from Acute and Chronic Occupational Exposures to Talc

#### TARGET ORGANS



#### LUNGS, RESPIRATORY SYSTEM

**Inhalation** ACUTE: Exposure to a large concentration of air-borne dust of this material may cause mechanical irritation of the mucous membranes and respiratory tract.  
CHRONIC: Repeated or prolonged inhalation of air-borne dust of this material may cause scarring of the lungs (pulmonary fibrosis), with shortness of breath, chronic cough, and respiratory assisted heart failure. Prolonged exposure to talc can produce symptomatic talc pneumoconiosis (talcosis).

**Skin Contact** ACUTE: Direct contact may cause dryness, or may cause mild irritation if an allergic predisposition exists.  
CHRONIC: Prolonged contact may cause dryness of the skin, or may cause mild irritation if an allergic pre-disposition exists

**Eye Contact** ACUTE: Direct contact with dust may cause mechanical irritation of the eyes.  
CHRONIC: Repeated exposure may cause conjunctivae inflammation.

**Ingestion** ACUTE: This material is considered to be harmless and inert when ingested.  
CHRONIC: Repeated ingestion of large doses of talc for 13 and 10 successive days by rabbits and mice revealed negative teratogenic and carcinogenic results.



# MATERIAL DATA SAFETY SHEET

## TALC

### Section 4. First Aid Measures

|              |   |
|--------------|---|
| Inhalation   | Remove from exposure area to fresh air. If breathing has stopped, perform artificial respiration and get medical attention immediately. Keep person warm and at rest. Treat symptomatically and supportively. |
| Skin Contact | Apply common skin moisturizers to relieve dryness. Irritations are uncommon; however, if irritation or redness develops, seek medical attention. Broken skin can be cleansed with mild soap and water.        |
| Eye Contact  | Wash eyes with large amounts of water or normal saline solution. If irritation or redness develops, seek medical attention.   |

### Section 5. Fire Fighting Measures

|              |  |
|--------------|--|
| Flammability | This product is <b>NOT</b> flammable, <b>NOT</b> reactive, <b>NOT</b> explosive, has <b>NO</b> flash point, and poses <b>NO</b> special hazards in the presence of fire. Firefighters require <b>NO</b> special protective equipment or precautions. |
|--------------|--|

### Section 6. Accidental Release Measures

|             |   |
|-------------|---|
| Small Spill | Use vacuum to clean up spillage. Place in sealed container.   |
| Large Spill | For large spills, shovel or sweep up (while keeping dispersion of dust in air to a minimum) and place into suitable sealed containers for reclamation or later disposal. Residue should be cleaned up using a high-efficiency particulate filter vacuum. The use of water wash-down is not recommended. Wet material can cause a surface used for walking to become extremely slippery. Talc is not considered a hazardous waste by RCRA criteria (40 CFR 261). |

### Section 7. Handling and Storage

|                    |   |
|--------------------|---|
| Handling & Storage | Handle in ways to minimize the creation of dust. Preserve product in sealed containers. |
|--------------------|---|

### Section 8. Exposure Controls & Personal Protection

|                     |  |
|---------------------|--|
| Personal Protection | Use NIOSH approved dust respirator. Use safety glasses or dust tight goggles. No special skin protection is usually required, but gloves should be worn by workers susceptible to skin irritation. |
|---------------------|--|



|          |   |
|----------|---|
| Controls | Provide local exhaust or process enclosure ventilation to meet published exposure limits (TLV). |
|----------|---|

### Section 9. Physical & Chemical Properties

|                  |   |
|------------------|---|
| Appearance       | White to grayish-white powder   |
| Odor             | Slight earthy odor.   |
| Flammability     | This product is <b>NOT</b> flammable, <b>NOT</b> reactive, <b>NOT</b> explosive, has <b>NO</b> flash point. |
| Specific Gravity | 2.8 (water = 1.0)   |
| Melting Point    | None  |



# MATERIAL DATA SAFETY SHEET

## TALC

|            |                                      |                           |                     |
|------------|--------------------------------------|---------------------------|---------------------|
| pH         | Slightly basic (10% slurry in water) |                           |                     |
| Solubility | Water: <1 mg/mL @ 21 C               | Acetone : <1 mg/mL @ 21 C | Alkalies: Insoluble |
|            | Ethanol: <1 mg/mL @ 21 C             | Cold acids: Insoluble     |                     |

### Section 10. Stability & Reactivity Data

**Stability** This product is stable, non-reactive, and non-corrosive.

**Incompatibility with various substances** Non reactive/none known.

### Section 11. Toxicological Information

**Toxicology** NIOSH Registry Number: WW2710000  
SAX Toxicity Evaluation: THR: Not available  
Carcinogenic Status:  
IARC: (2006 in preparation) Has concluded that perineal use of talc-based body powder is possibly carcinogenic to humans (Group 2B). This is not a route of exposure relevant for workers and applies to one specific use of talc only.  
IARC: (2006 in preparation) Inhaled talc not containing asbestos or asbestiform fibres not classifiable as a human carcinogen (Group 3)  
OSHA: Not listed.  
ACGIH: A4 – Not Classifiable as a Human Carcinogen  
NTP: Not listed. A 2-year inhalation study demonstrated clear evidence of carcinogenic activity in female rats at exposure levels of 18 mg/m<sup>3</sup>. Some evidence of carcinogenic activity was observed in male rats at the same level. No evidence of carcinogenic activity was found in mice (NTP TR-421).  
Tumorigenic Data:  
TCLo: ihl-rat 11 mg/m<sup>3</sup>/1Y-I  
TDLo: imp-rat 200 mg/kg  
Other Toxicity Data:  
Skin and Eye Irritation Data: skn-hmn 300 ug/3D-I MLD  
Teratogenicity (Reproductive Effects Data): Not available.  
Mutation Data: Not available.

### Section 12. Ecological Information

#### Ecological Data

| Species      | Alga (( <i>Selenastrum capricornutum</i> ))                      | <i>Daphnia Magna</i> | <i>Daphnia Magna</i>    |
|--------------|--|----------------------|-------------------------|
| Test         | Growth inhibition  | Acute immobilization | Reproduction            |
| Endpoint     | Growth rate<br>48hr-EC50 48hr-NOEC<br>AUG<br>72hr-EC50 72hr-NOEC | 48hr-EC50            | 21 day-EC50 21 day-NOEC |
| Conc. (mg/L) |  |                      |                         |
| FY           |  |                      |                         |
| References   |  |                      |                         |

\*AUG=Area Under Growth curve

### Section 13. Disposal Considerations





# MATERIAL DATA SAFETY SHEET TALC

**Waste Disposal Information** Talc is not considered a hazardous waste by RCRA criteria (40 CFR 261). Dry material can usually be land-filled. State and Local regulations/restrictions are complex and may differ from Federal regulations. Responsibility for proper waste disposal is with the owner of the waste.

## Section 14. Transport Information

**Transport Information** U.S. Department of Transportation - DOT: No classification assigned  
CANADIAN Transportation of Dangerous Goods: No classification assigned  
LAND Transport - ADR/RID: No classification assigned  
AIR Transport - IATA/ICAO: No classification assigned (International Air Transport Association/International Civil Aviation Organization)  
MARITIME Transport - IMDG: No classifications assigned International Maritime Dangerous Goods)  
HARMONIZED Tariff Code: Talc – crushed or powdered. 2526.20.00. (Stat. Suffix 00)  
EPA TSCA 12(B) Export Notification: Not listed

## Section 15. Regulatory Information

**Chemical Inventories** EPA TSCA Status: Listed (CAS # 14807-96-6) EINECS (European No: 238-877-9)  
CEPA Domestic Substance List – DSL: Listed CEPA Non-domestic substance List – NDSL: Not listed  
AICS (Australian – NICNAS) ECL (Korean No: KE-32773)  
SWISS (Giftliste No: G-6939) PICCS (Philippines)  
ENCS/MITI (Japan) – Talc exempt IECSC (China): Listed

### Other Pertinent Classifications/Regulations

CALIFORNIA PROP 65 Status: Talc not listed  
STATE RIGHT-TO-KNOW: Talc listed – Illinois; Massachusetts; New Jersey; Pennsylvania; Florida  
CLEAN AIR ACT – Ozone Depleting Chemicals (ODC's): None  
CONEG Approved Packaging: Yes  
NFPA RATINGS: (Scale 0-4) Health = 1, Fire = 0, Reactivity = 0

NPCA: National Paint and Coatings Association – Hazardous Material Identification System (HMIS)

HEALTH: 1\* (Chronic Potential)  
FLAMMABILITY: 0  
PHYSICAL: 0  
PERSONAL PROTECTION: dust respirator, glasses or goggles, gloves

## Section 16. Other Information

**Label Hazard Warning** CAUTION - PROLONGED EXCESSIVE INHALATION MAY CAUSE LUNG INJURY

**Label Precautions** UTILIZE DUST RESPIRATOR AND EXHAUST VENTILATION. REFER TO MSDS FOR COMPLETE DETAILS



TYPICAL APPERANCE OF PRODUCT LABEL





## MATERIAL DATA SAFETY SHEET TALC

**Primary  
References  
for Key Data**

ACGIH - Documentation of TLV's 2001  
 OSHA - Chemical Sampling Information: Talc (Containing no asbestos) (Revised 1/15/1999)  
 OSHA - TALC (Containing no asbestos). OSHA comments from the June 19, 1988 Final Rule on Air Contaminants Project extracted from 54FR2324 *et. seq.*  
 OSHA - Compliance Interpretation Letter dated August 22, 2000 regarding talc products containing less than 1% quartz.  
 OSHA - Guidelines for Employer Compliance (Advisory) 1910.1200 App E  
 NIOSH - Pocket Guide to Chemical Hazards. Talc (containing no asbestos and less than 1% quartz).  
 NIOSH - REL's and General Recommendations for Safety and Health. [TALC (containing no asbestos).  
 AIHA - Hygienic Guides Series – Talc (1982)  
 IARC - Talc Vol.: 42 (1987) (p.185) 5. Summary of Data Reported and Evaluation; Supplement 7: (1987) (p.349) Talc Not Containing Asbestiform Fibers (Group 3).  
 CCOHS – Database MSDS FTSS. Network Version 2002.  
 NTP – RoC/NIEHS Database. Network Version 2002.

**Glossary**

ACGIH – American Conference of Governmental Industrial Hygienists  
 AIHA – American Industrial Hygiene Association  
 CCOHS – Canadian Centre for Occupational Health and Safety  
 IARC – International Agency for Research on Cancer  
 NIOSH – National Institute of Occupational Safety and Health  
 NTP – National Toxicological Program  
 OSHA – Occupational Safety and Health Association  
 PEL – Permissible Exposure Level  
 TLV – Threshold Limit Value  
 TWA – Time Weighted Average

**Important  
Notice**

Luzenac America, Inc. provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose.

**Issued by**

Shripal Sharma  
 Global talc Regulatory Affairs Manager  
 Luzenac America, Inc.  
 E-mail: shripal.sharma@riotinto.com  
 Phone: 1-303-713-5227

# **EXHIBIT 35**



# MATERIAL DATA SAFETY SHEET TALC

Plaintiff's Exhibit  
No.

P-37

exhibitsticker.com

| Section 1. Product and Company Identification      |   |  |                 |
|--|---|--|-----------------|
| <b>Product Names</b>                               |   |  |                 |
| Grade 25 USP                                       | Imperial 180 USP  | Imperial 200 USP   |                 |
| Imperial 250 USP                                   | Imperial 400 USP  | Imperial 400Y USP  |                 |
| Imperial 500 USP                                   | Imperial 1885L USP/BC   | Imperial 1889L USP/BP/EP/BC                                  |                 |
| Imperial 1890 USP/BC                               | Imperial 1892L USP/BP/EP/BC   | Olympic H USP  |                 |
| Suprafino HP USP                                   | Supra H USP   | Olympic HY USP   |                 |
| Supreme H USP                                      |   |  |                 |
| <b>Synonyms</b> Talcum powder, Soapstone, Steatite |   |  |                 |
| <b>Chemical Name</b>                               | Talc ; Hydrous magnesium silicate   | <b>CAS#</b>  | 14807-96-6      |
|  |   | <b>Chemical Family</b>                                       | Phyllosilicates |
| <b>Manufacturer</b>                                | Luzenac America, Inc.<br>8051 E. Maplewood Avenue, Bldg 4<br>Greenwood Village, CO 80111<br>Toll-free +1-800-325-0299 (General Information) | <b>Emergency Health Information (24 hrs)</b><br>303-623-5716 |                 |

| Section 2. Composition/Information on Ingredients |             |                    |  |
|---|-------------|--------------------|--|
| <b>Substance</b>                                  | <b>CAS#</b> | <b>% by Weight</b> | <b>TLV - TWA</b>                             |
| Talc  | 14807-96-6  | 98-100             | 2 mg/m3 respirable fraction (ACGIH)          |
| Dolomite  | 16389-88-1  | 0-2                | Use Talc TLV for total exposure measurements |

| Section 3. Health Hazards Identification and Emergency Overview   |   |
|---|---|
| <b>Emergency Overview</b>   | Under normal conditions of use, this product is not expected to create any unusual emergency hazards. This product is <b>NOT</b> flammable, <b>NOT</b> reactive, <b>NOT</b> explosive, has <b>NO</b> flash point, and poses <b>NO</b> special hazards in the presence of fire.  |
| <p><b>Potential Health Effects from Acute and Chronic Occupational Exposures to Talc</b></p> <p><b>TARGET ORGANS</b></p> <div style="text-align: center;"> </div> <p><b>LUNGS, RESPIRATORY SYSTEM</b></p> |   |
| <b>Inhalation</b>   | <p>ACUTE: Exposure to a large concentration of air-born dust of this material may cause mechanical irritation of the mucous membranes and respiratory tract.</p> <p>CHRONIC: Repeated or prolonged inhalation of air-born dust of this material may cause scarring of the lungs (pulmonary fibrosis), with shortness of breath, chronic cough, and respiratory assisted heart failure. Prolonged exposure to talc can produce symptomatic talc pneumoconiosis (talcosis).</p> |
| <b>Skin Contact</b>   | <p>ACUTE: Direct contact may cause dryness, or may cause mild irritation if an allergic predisposition exists.</p> <p>CHRONIC: Prolonged contact may cause dryness of the skin, or may cause mild irritation if an allergic pre-disposition exists</p>  |
| <b>Eye Contact</b>  | <p>ACUTE: Direct contact with dust may cause mechanical irritation of the eyes.</p> <p>CHRONIC: Repeated exposure may cause conjunctivae inflammation.</p>  |
| <b>Ingestion</b>  | <p>ACUTE: This material is considered to be harmless and inert when ingested.</p> <p>CHRONIC: Repeated ingestion of large doses of talc for 13 and 10 successive days by rabbits and mice revealed negative teratogenic and carcinogenic results.</p>   |



# MATERIAL DATA SAFETY SHEET




## TALC

| Section 4. First Aid Measures |   |
|-------------------------------|---|
| <b>Inhalation</b>             | Remove from exposure area to fresh air. If breathing has stopped, perform artificial respiration and get medical attention immediately. Keep person warm and at rest. Treat symptomatically and supportively. |
| <b>Skin Contact</b>           | Apply common skin moisturizers to relieve dryness. Irritations are uncommon; however, if irritation or redness develops, seek medical attention. Broken skin can be cleansed with mild soap and water.        |
| <b>Eye Contact</b>            | Wash eyes with large amounts of water or normal saline solution. If irritation or redness develops, seek medical attention.   |

| Section 5. Fire Fighting Measures |  |
|-----------------------------------|--|
| <b>Flammability</b>               | This product is <b>NOT</b> flammable, <b>NOT</b> reactive, <b>NOT</b> explosive, has <b>NO</b> flash point, and poses <b>NO</b> special hazards in the presence of fire. Firefighters require <b>NO</b> special protective equipment or precautions. |

| Section 6. Accidental Release Measures |   |
|--|---|
| <b>Small Spill</b>                     | Use vacuum to clean up spillage. Place in sealed container.   |
| <b>Large Spill</b>                     | For large spills, shovel or sweep up (while keeping dispersion of dust in air to a minimum) and place into suitable sealed containers for reclamation or later disposal. Residue should be cleaned up using a high-efficiency particulate filter vacuum. The use of water wash-down is not recommended. Wet material can cause a surface used for walking to become extremely slippery. Talc is not considered a hazardous waste by RCRA criteria (40 CFR 261). |

| Section 7. Handling and Storage |   |
|---------------------------------|---|
| <b>Handling &amp; Storage</b>   | Handle in ways to minimize the creation of dust. Preserve product in sealed containers. |

| Section 8. Exposure Controls & Personal Protection  |  |
|---|--|
| <b>Personal Protection</b>  | Use NIOSH approved dust respirator. Use safety glasses or dust tight goggles. No special skin protection is usually required, but gloves should be worn by workers susceptible to skin irritation. |
| <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p>Dust Respirator</p> </div> <div style="text-align: center;">  <p>Safety Glasses</p> </div> <div style="text-align: center;">  <p>Gloves</p> </div> </div> |  |
| <b>Controls</b>   | Provide local exhaust or process enclosure ventilation to meet published exposure limits (TLV).  |

| Section 9. Physical & Chemical Properties |   |
|---|---|
| <b>Appearance</b>                         | White to grayish-white powder   |
| <b>Odor</b>                               | Slight earthy odor.   |
| <b>Flammability</b>                       | This product is <b>NOT</b> flammable, <b>NOT</b> reactive, <b>NOT</b> explosive, has <b>NO</b> flash point. |
| <b>Specific Gravity</b>                   | 2.8 (water = 1.0)   |
| <b>Melting Point</b>                      | None  |



# MATERIAL DATA SAFETY SHEET

## TALC

|            |                                      |                           |                     |
|------------|--------------------------------------|---------------------------|---------------------|
| pH         | Slightly basic (10% slurry in water) |                           |                     |
| Solubility | Water: <1 mg/mL @ 21 C               | Acetone : <1 mg/mL @ 21 C | Alkalies: Insoluble |
|            | Ethanol: <1 mg/mL @ 21 C             | Cold acids: Insoluble     |                     |

| Section 10. Stability & Reactivity Data |  |
|---|--|
| Stability                               | This product is stable, non-reactive, and non-corrosive. |
| Incompatibility with various substances | Non reactive/none known.                                 |

| Section 11. Toxicological Information |   |
|---------------------------------------|---|
| Toxicology                            | <p>NIOSH Registry Number: WW2710000<br/> SAX Toxicity Evaluation: THR: Not available<br/> Carcinogenic Status:<br/> IARC: (2006 in preparation) Has concluded that perineal use of talc-based body powder is possibly carcinogenic to humans (Group 2B). This is not a route of exposure relevant for workers and applies to one specific use of talc only.<br/> IARC: (2006 in preparation) Inhaled talc not containing asbestos or asbestiform fibres not classifiable as a human carcinogen (Group 3)<br/> OSHA: Not listed.<br/> ACGIH: A4 – Not Classifiable as a Human Carcinogen<br/> NTP: Not listed. A 2-year inhalation study demonstrated clear evidence of carcinogenic activity in female rats at exposure levels of 18 mg/m<sup>3</sup>. Some evidence of carcinogenic activity was observed in male rats at the same level. No evidence of carcinogenic activity was found in mice (NTP TR-421).<br/> Tumorigenic Data:<br/> TCLo: ihl-rat 11 mg/m<sup>3</sup>/1Y-I<br/> TDLo: imp-rat 200 mg/kg<br/> Other Toxicity Data:<br/> Skin and Eye Irritation Data: skn-hmn 300 ug/3D-I MLD<br/> Teratogenicity (Reproductive Effects Data): Not available.<br/> Mutation Data: Not available.</p> |

| Section 12. Ecological Information |   |
|------------------------------------|---|
| Ecological Data                    |   |
| Species                            | Alga ( <i>Selenastrum capricornutum</i> ) <i>Daphnia Magna</i> <i>Daphnia Magna</i> |
| Test                               | Acute   |
| Endpoint                           | Growth inhibition    immobilization    Reproduction                                 |
|                                    | Growth rate    48hr-EC50    21 day-EC50    21 day-NOEC                              |
|                                    | 48hr-EC50    48hr-NOEC    48hr-EC50    48hr-NOEC                                    |
| Conc. (mg/L)                       |   |
| FY                                 |   |
| References                         |   |

\*AUG=Area Under Growth curve

| Section 13. Disposal Considerations |
|-------------------------------------|
|-------------------------------------|



# MATERIAL DATA SAFETY SHEET TALC

**Waste Disposal Information** Talc is not considered a hazardous waste by RCRA criteria (40 CFR 261). Dry material can usually be land-filled. State and Local regulations/restrictions are complex and may differ from Federal regulations. Responsibility for proper waste disposal is with the owner of the waste.

## Section 14. Transport Information

**Transport Information** U.S. Department of Transportation - DOT: No classification assigned  
CANADIAN Transportation of Dangerous Goods: No classification assigned  
LAND Transport - ADR/RID: No classification assigned  
AIR Transport - IATA/ICAO: No classification assigned (International Air Transport Association/International Civil Aviation Organization)  
MARITIME Transport - IMDG: No classifications assigned International Maritime Dangerous Goods)  
HARMONIZED Tariff Code: Talc – crushed or powdered. 2526.20.00. (Stat. Suffix 00)  
EPA TSCA 12(B) Export Notification: Not listed

## Section 15. Regulatory Information

**Chemical Inventories** EPA TSCA Status: Listed (CAS # 14807-96-6) EINECS (European No: 238-877-9)  
CEPA Domestic Substance List – DSL: Listed CEPA Non-domestic substance List – NDSL: Not listed  
AICS (Australian – NICNAS) ECL (Korean No: KE-32773)  
SWISS (Giftliste No: G-6939) PICCS (Philippines)  
ENCS/MITI (Japan) – Talc exempt IECSC (China): Listed

### Other Pertinent Classifications/Regulations

CALIFORNIA PROP 65 Status: Talc not listed  
STATE RIGHT-TO-KNOW: Talc listed – Illinois; Massachusetts; New Jersey; Pennsylvania; Florida  
CLEAN AIR ACT – Ozone Depleting Chemicals (ODC's): None  
CONEG Approved Packaging: Yes  
NFPA RATINGS: (Scale 0-4) Health = 1, Fire = 0, Reactivity = 0

NPCA: National Paint and Coatings Association – Hazardous Material Identification System  
HMIS)

HEALTH: 1\* (Chronic Potential)  
FLAMMABILITY: 0  
PHYSICAL: 0  
PERSONAL PROTECTION: dust respirator, glasses or goggles, gloves

## Section 16. Other Information

**Label Hazard Warning** CAUTION - PROLONGED EXCESSIVE INHALATION MAY CAUSE LUNG INJURY

**Label Precautions** UTILIZE DUST RESPIRATOR AND EXHAUST VENTILATION. REFER TO MSDS FOR COMPLETE DETAILS



TYPICAL APPEARANCE OF PRODUCT LABEL





# MATERIAL DATA SAFETY SHEET TALC

## Primary References for Key Data

ACGIH - Documentation of TLV's 2001  
 OSHA - Chemical Sampling Information: Talc (Containing no asbestos) (Revised 1/15/1999)  
 OSHA - TALC (Containing no asbestos). OSHA comments from the June 19, 1988 Final Rule on Air Contaminants Project extracted from 54FR2324 *et. seq.*  
 OSHA - Compliance Interpretation Letter dated August 22, 2000 regarding talc products containing less than 1% quartz.  
 OSHA - Guidelines for Employer Compliance (Advisory) 1910.1200 App E  
 NIOSH - Pocket Guide to Chemical Hazards. Talc (containing no asbestos and less than 1% quartz).  
 NIOSH - REL's and General Recommendations for Safety and Health. [TALC (containing no asbestos).  
 AIHA - Hygienic Guides Series – Talc (1982)  
 IARC - Talc Vol.: 42 (1987) (p.185) 5. Summary of Data Reported and Evaluation; Supplement 7: (1987) (p.349) Talc Not Containing Asbestiform Fibers (Group 3).  
 CCOHS – Database MSDS FTSS. Network Version 2002.  
 NTP – RoC/NIEHS Database. Network Version 2002.

## Glossary

ACGIH – American Conference of Governmental Industrial Hygienists  
 AIHA – American Industrial Hygiene Association  
 CCOHS – Canadian Centre for Occupational Health and Safety  
 IARC – International Agency for Research on Cancer  
 NIOSH – National Institute of Occupational Safety and Health  
 NTP – National Toxicological Program  
 OSHA – Occupational Safety and Health Association  
 PEL – Permissible Exposure Level  
 TLV – Threshold Limit Value  
 TWA – Time Weighted Average

## Important Notice

Luzenac America, Inc. provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose.

## Issued by

Shripal Sharma  
 Global talc Regulatory Affairs Manager  
 Luzenac America, Inc.  
 E-mail: shripal.sharma@riotinto.com  
 Phone: 1-303-713-5227

# **EXHIBIT 36**





DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

APR 1 - 2014

Samuel S. Epstein, M.D.  
Cancer Prevention Coalition  
University of Illinois at Chicago  
School of Public Health, MC 922  
2121 West Taylor Street, Rm. 322  
Chicago, Illinois 60612

RE: Docket Numbers 94P-0420 and FDA-2008-P-0309-0001/CP

Dear Dr. Epstein:

This letter is in response to your two Citizen Petitions dated November 17, 1994 and May 13, 2008, requesting that the Food and Drug Administration (FDA or the Agency) require a cancer warning on cosmetic talc products. Your 1994 Petition requests that all cosmetic talc bear labels with a warning such as "Talcum powder causes cancer in laboratory animals. Frequent talc application in the female genital area increases the risk of ovarian cancer." Additionally, your 2008 Petition requests that cosmetic talcum powder products bear labels with a prominent warning such as: "Frequent talc application in the female genital area is responsible for major risks of ovarian cancer." Further, both of your Petitions specifically request, pursuant to 21 CFR 10.30(h)(2), a hearing for you to present scientific evidence in support of this petition.

We have carefully considered both of your Petitions. We are committed to the protection of the public health and share your interest in reducing the risk of ovarian cancer. Current regulations state that cosmetic products shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with a product. FDA may publish a proposal to establish a regulation prescribing a warning statement on behalf of a petitioner if the petition is supported by adequate scientific basis on reasonable grounds.

After careful review and consideration of the information submitted in your Petitions, the comments received in response to the Petitions, and review of additional scientific information, this letter is to advise you that FDA is denying your Petitions. FDA did not find that the data submitted presented conclusive evidence of a causal association between talc use in the perineal area and ovarian cancer.

For this reason and for the additional reasons described below, FDA is denying your Petitions.

Plaintiff's Exhibit  
No.

P-47

exhibitstickers.com

Page 2 – Dr. Epstein

## **I. Discussion**

The basis of your request, throughout both Petitions, can be summarized as comprising three major points:

1. Talc may be associated with asbestos.
2. Talc is a carcinogen based on the findings of a 1993 National Toxicology Program study.
3. Epidemiological studies confirm the causal relation between genital application of talc and ovarian cancer, and the protective effect of tubal ligation or hysterectomy, preventing the translocation of talc to the ovary.

As the points you raise in your Petitions concern the chemistry and toxicology of talc, the epidemiology associated with talc use, and the etiology of ovarian cancer, commensurate reviews were conducted to assess your request.

### Chemistry Findings:

Asbestos is a known carcinogen and your first major point is that talc may be associated with asbestos. As evidence that talc cosmetic products contain asbestos, you first cite a 1968 survey of 22 talcum products that found fiber content averaging 19% in all 22 products. This author further concludes that “the fibrous material was predominantly talc but probably contained minor amounts of tremolite, anthophyllite, and chrysotile [asbestos-like fibers] as these are often present in fibrous talc mineral deposits ...”

You then cite a follow up study from 1971-1975 that examined 21 samples of consumer talcums and powder and concluded that cosmetic grade talc was not used exclusively in these products. This study found the presence of asbestiform anthophyllite and tremolite, chrysotile, and quartz. From these two citations, one may infer that currently available talc-containing cosmetic products are presently contaminated with asbestos, a known carcinogen. Unfortunately, you did not present any original data on the chemical composition of talc currently being used in cosmetics talc products or data linking these findings to currently used talc.

It has been reported in the scientific literature that most talc products in world trade are impure as a result of the geological processes involved in the formation of talc deposits. Further, talc containing asbestos fibers such as tremolite asbestos or chrysotile are sometimes encountered. However, large deposits of high purity, asbestos-free talc do exist and talc purification techniques have been developed which can be used to improve talc quality. Thus, while it has been reported in the past that cosmetic talc has been contaminated with asbestos, it has been also reported that asbestos-free talc deposits do exist. In addition, techniques do exist for the purification of talc in order to improve its quality. You have not provided evidence that asbestos contaminated talc-containing cosmetic products are currently being marketed, since the data submitted is almost 40 years old.



Page 3 – Dr. Epstein

Because safety questions about the possible presence of asbestos in talc are raised periodically, in 2009 FDA conducted an exploratory survey of currently marketed cosmetic-grade raw material talc and finished cosmetic products containing talc. This survey analyzed cosmetic-grade raw material talc from four suppliers out of a possible group of nine suppliers we had requested talc samples from, along with thirty-four talc-containing cosmetic products currently available in the Washington, D.C. metropolitan area for the presence of asbestos. In order to cover as broad a product range as possible, samples identified for testing included low, medium, and high priced products, along with some from “niche” markets. The cosmetic products identified as containing talc included eye shadow, blush, foundation, face powder, and body powder.

The survey found no asbestos fibers or structures in any of the samples of cosmetic-grade raw material talc or cosmetic products containing talc. While FDA found this data informative, the results were limited by the fact that only four suppliers submitted samples and by the number of products tested. They do not prove that all talc-containing cosmetic products currently marketed in the United States are free of asbestos contamination. As always, when potential public health concerns are raised, we will continue to monitor for new information and take appropriate actions to protect the public health. You may wish to see more on this survey on our website at <http://www.fda.gov/Cosmetics/ProductandIngredientSafety/SelectedCosmeticIngredients/ucm293184.htm>.

#### Toxicology Findings:

Your second major point is that talc is a carcinogen with or without the presence of asbestos-like fibers. The basis to this claim is that in 1993, the National Toxicology Program (NTP) published a study on the toxicity of non-asbestiform talc and found clear evidence of carcinogenic activity.

This NTP report concluded that cosmetic-grade talc caused tumors in animals, even though no asbestos-like fibers were found. The report made the following observations:

- There was some evidence of carcinogenic activity in non-asbestiform talc from inhalation studies in male rats based on an increased incidence of benign or malignant pheochromocytomas of the adrenal gland.
- There was clear evidence of carcinogenic activity of talc in female rats based on increased incidences of alveolar/bronchiolar adenomas and carcinomas of the lung and benign or malignant pheochromocytomas of the adrenal gland.
- There was no evidence of carcinogenic activity of talc in male or female mice exposed to 6 or 18 mg/cubic meter.

However, this study lacks convincing scientific support because of serious flaws in its design and conduct, including:

- The investigators used micronized talc instead of consumer-grade talc resulting in the experimental protocol not being reflective of human exposure conditions in terms of particle size.

Page 4 – Dr. Epstein

- Investigators conceded that they had problems with the aerosol generation system; whereby, the target aerosol concentrations were either excessive or not maintained during 26 of the 113-122 weeks of the study.
- The study did not include positive and negative dust controls which would have permitted an “exact assessment” of the talc’s carcinogenicity relative to the two control dusts.

In light of these shortcomings, a panel of experts at the 1994 ISRTP/FDA workshop declared that the 1993 NTP study has no relevance to human risk.

In addition, we reviewed relevant toxicity literature (consisting of 15 articles from 1980 to 2008), not cited in your Petitions, to determine if there was additional support at this point in time to for your suggested warning label. Scientific literature on studies of acute exposure effects, subchronic exposure effects, chronic exposure or carcinogenicity effects, developmental or reproductive toxicity, and genotoxicity effects were reviewed. As a result of the review of this relevant literature, FDA did not find enough additional support at this point in time for your suggested warning label.

Epidemiology and Etiology Findings:

Your third major point is that epidemiological studies confirm the causal relation between genital application of talc and ovarian cancer, and the protective effect of tubal ligation or hysterectomy, preventing the translocation of talc to the ovary.

After consideration of the scientific literature submitted in support of both Citizen Petitions, FDA found:

- 1 The exposure to talc is not well-characterized; it is not known if the talc referred to in the scientific studies was free of asbestos contamination; various consumer brands or lots of talc were not identified; and contamination of talc by asbestiform minerals or other structurally similar compounds was not ruled out.
- 2 Several of the studies acknowledge biases in the study design and no single study has considered all the factors that potentially contribute to ovarian cancer, including selection bias and/or uncontrolled confounding that result in spurious positive associations between talc use and ovarian cancer risk.
- 3 Results of case-controls studies do not demonstrate a consistent positive association across studies; some studies have found small positive associations between talc and ovarian cancer but the lower confidence limits are often close to 1.0 and dose-response evidence is lacking.
- 4 A cogent biological mechanism by which talc might lead to ovarian cancer is lacking; exposure to talc does not account for all cases of ovarian cancer; and

Page 5- Dr. Epstein

- 5 there was no scientific consensus on the proportion of ovarian cancer cases that may be caused by talc exposure.
- 6 The conclusion of the International Agency for Research on Cancer that epidemiological studies provide limited evidence for the carcinogenicity of perineal use of talc based body powder and the IARC classification of body-powder talc as group-2B, a possible carcinogen to human beings, is persuasive, but the results of the Nurses' Health Study, a large prospective cohort study, revealed no overall association with ever talc use and epithelial ovarian cancer.

Per the etiology review, approximately 10% of epithelial ovarian cancers are associated with inherited mutations. The remaining 90% of epithelial ovarian cancers are not related to these genetic mutations are non-hereditary. They have been historically classified based on histology as borderline/low malignant potential, serous, endometrioid, mucinous, and clear-cell.

Two theories have historically dominated on the cause of epithelial ovarian cancer and these are the "incessant ovulation hypothesis" and the "gonadotropin hypothesis." In addition to these endogenous factors, the role of exogenous factors via retrograde transport of noxious substances (e.g. carcinogens, particulates such as talc and asbestos, endometriosis and infectious agents) from the vagina and uterus into the Fallopian Tubes and peritoneal cavity have been studied extensively as a possible risk factor for ovarian cancer.

While there exists no direct proof of talc and ovarian carcinogenesis, the potential for particulates to migrate from the perineum and vagina to the peritoneal cavity is indisputable. It is, therefore, plausible that perineal talc (and other particulate) that reaches the endometrial cavity, Fallopian Tubes, ovaries and peritoneum may elicit a foreign body type reaction and inflammatory response that, in some exposed women, may progress to epithelial cancers. However, there has been no conclusive evidence to support causality.

The best evidence for an association or causal relationship between genital talc exposure and ovarian cancer comes from epidemiologic data which show a statistically significant but modest increased risk of epithelial ovarian cancer, especially with serous histology, among women with a history of genital dusting with talcum powder. While the growing body of evidence to support a possible association between genital talc exposure and serous ovarian cancer is difficult to dismiss, the evidence is insufficient for FDA to require as definitive a warning as you are seeking.

#### Request for hearing

In addition to your request for a warning label, you also requested a hearing, under 21 CFR 10.30(h)(2), so that you can present scientific evidence in support of your petitions.



Page 6 – Dr. Epstein

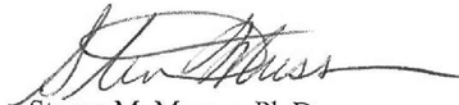
Under this regulation, FDA may deny a citizen petition request for a hearing if the data and information submitted (even if accurate), are insufficient to justify the determination urged. In consideration of your request, we conducted an expanded literature search dating from the filing of the petition in 2008 through January 2014. The results of this search failed to identify any new compelling literature data or new scientific evidence.

Since we find that the data and information are insufficient to justify the determination you request and we did not identify any new compelling literature data or new scientific evidence, FDA is also denying your hearing request.

## **II. Conclusion**

FDA appreciates the goals of the Cancer Prevention Coalition and FDA supports the goal of reducing the rate of ovarian cancer. Although FDA is denying the Cancer Prevention Coalition's petitions for the reasons discussed above, the Agency shares your commitment to the public health.

Sincerely,

A handwritten signature in black ink, appearing to read "Steven M. Musser", with a long horizontal flourish extending to the right.

Steven M. Musser, Ph.D.  
Deputy Director for Scientific Operations  
Center for Food Safety  
and Applied Nutrition

Drafted: J. Gasper, OCAC, 2/28/14  
Comments: L. Katz, OCAC, 3/3/14  
Revised: J. Gasper, OCAC, 3/4/14  
Cleared: N.Sadrieh, OCAC, 3/4/14  
Cleared: LMKatz, OCAC, 3/5/14  
Reviewed: FHogue, OCAC: 3/6/14  
Cleared by: Musser: 3/13/14  
F/T: SRussell, OCAC 3/18/14

# **EXHIBIT 37**



## [Letter of proposal to FDA and NIEHS/NIH]

The FDA has legislative responsibility for direct regulation of unsafe ingredients in cosmetics under the Food, Drug and Cosmetic Act. In 1994, as a result of concerns regarding the 1993 NTP animal study and recently published epidemiological studies linking talc and ovarian cancer, the FDA and the International Society for Regulatory Toxicology and Pharmacology co-sponsored a workshop to discuss the issues and to see whether they could arrive at any consensus views on how they should be interpreted. Twenty FDA scientists participated, along with numerous scientists from academia, industry, cancer research institutions, NIEHS, NCI, and other organizations.

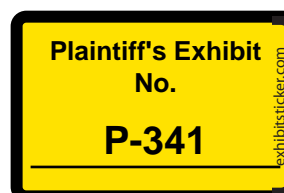
At the beginning of the workshop, Dr. John Bailey, Director of FDA's Office of Cosmetics and Colors, presented the "Introduction: Overview - Scope of the Workshop", in which he stated:

“ . . . I think it is reasonable to expect by the end of the workshop to have a discussion or even to reach a consensus of the many scientific and medical experts that are participating in and attending this meeting about the relevance of the recent reports to the safety of talc to human health risks.”

At the conclusion of the Workshop, an Executive Summary was prepared by the Rapporteur, Dr. Jelleff Carr (Talc: Consumer Uses and Health Perspectives" in *Reg. Tox. Pharm.* 21(2):211-60 (1995). With regard to the ovarian cancer issue, Dr. Carr explains the consensus that was reached:

“Following the many issues raised by all presenters, the ensuing discussion generally agreed that while some weak association between talc exposure and ovarian tumors has been reported, it was not sufficient warning for concern.”

“The possibility of an association of talc exposure and ovarian cancer is an important hypothesis of potential public health importance. However, this association remains a research hypothesis whose verification or falsification needs additional study.”



“[E]pidemiologic studies have provided weak and conflicting risk signals for this association and it is unlikely that further studies may prove adequate to raise concern at a level sufficient to warrant regulatory or public health measures.”

Indeed, the prediction by the panel that additional epidemiology studies on this subject would prove inadequate to clearly define an association between the perineal application of talcum powder and an increased risk of ovarian cancer was accurate. When NTP began their review of non-asbestiform talc in 2000, eight additional epidemiologic studies were published and evaluated by NTP. The eight additional studies continued to provide weak and conflicting risk signals with no consistent trend by duration or frequency of talc use. Appropriately, the NTP Board of Scientific Counselors Subcommittee concluded that the listing of cosmetic talc was not scientifically justified and voted 7-3 not to list talc (not containing asbestiform fibers).

Since the conclusion of NTP review in 2000, only one additional case-control study has been published (Central Valley of California). Not surprisingly, this additional epidemiological study provided no new information of scientific utility.

Given all this scrutiny during the last decade of “cosmetic talc” and its association with ovarian cancer, Luzenac cannot imagine that an additional review by NTP would result in a reversal of consensus about the scientific validity of this hypothesized association. But given the sensitive nature of this very serious women’s health issue and the lingering suspicions concerning cosmetic talc as a possible risk factor, Luzenac would like to propose a remedy to FDA and NIEHS/NIH that would eliminate the need for any further debate and review of this issue.

We propose:

1. The talc industry in the United States will voluntarily phase-out the production and sale of all cosmetic talc products used specifically for consumer dusting powders, body powders, baby powders, and any other loose powder products that might reasonably be anticipated to be used by women for perineal application.

2. In cooperation with domestic cosmetic and pharmaceutical member companies of the CTFA, this product phase-out will occur within XX months of acceptance of these proposals by NTP and FDA.
3. The voluntary withdrawal would not include such products as medicated foot powders where it would not be reasonably anticipated that the product would be used for perineal dusting; nor would the withdrawal include cosmetic talc products sold for make-up, lipstick, eye-shadow and cream foundations where it would not be reasonably anticipated that the product(s) would be used for perineal dusting.
4. The CTFA will assist the FDA in developing an appropriate cosmetic warning label for any dusting or body powders containing talc which are produced or imported after an established date. The label would warn the consumer the product is not to be used for genital dusting and would report of the possible association between genital dusting and ovarian cancer. The warning label would be mandatory.

The result of these proposed actions would:

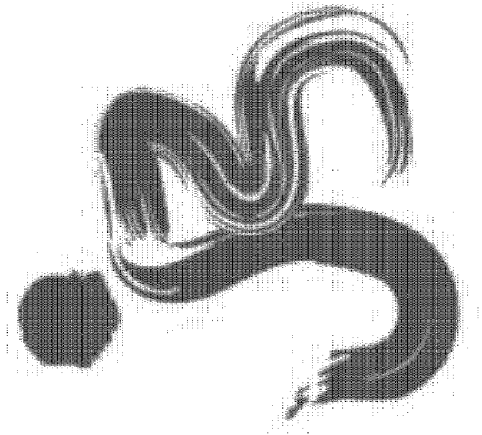
1. In very short order, virtually eliminate the exposure potential in the general population to dusting powders containing talc. As more and more dusting powders have already been re-formulated with increased levels of cornstarch, the proposed actions would accelerate these product conversions.
2. Eliminating the perineal exposure potential for women suspends the need for NTP to proceed with a review of cosmetic talc. Given the weakness of the science, it is improbable that a listing recommendation would have resulted – meaning the debate on this theorized association would continue unresolved. These voluntary actions proposed by the talc industry and CTFA member companies would end the debate and allow researchers to focus on other more plausible risk factors.

## IMERYS284935

### Metadata

|                        |                    |          |
|------------------------|--------------------|----------|
| <b>Author</b>          | rzazensk           | ORIGINAL |
| <b>Custodian</b>       | Zazenski, Rich;    | ORIGINAL |
| <b>DateCreated</b>     | 11/30/2004 9:03 PM | ORIGINAL |
| <b>OtherCustodians</b> | Zazenski, Rich;    | ORIGINAL |

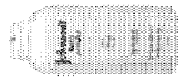
# **EXHIBIT 38**



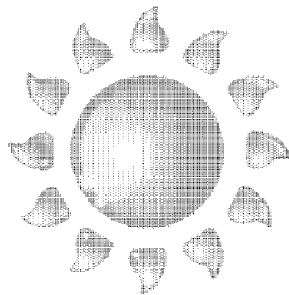
# **JOHNSON'S® Baby Powder**

## **2010 Media Recommendation**





# 2010 Powder Program Overview



## Objective:

- Recruit new and younger users by giving them a compelling reason to use JOHNSON'S® Baby Powder

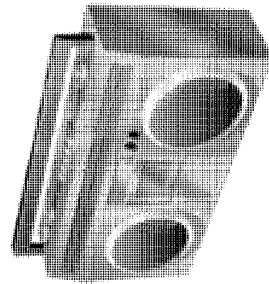
## Key Strategies and Tactics:

- Target overweight women living in hot climates during key summer season
- Launch campaign with an insertion in People Magazine within weight loss edit and use Weight Watchers Magazine and Everyday with Rachael Ray to target women who are overweight
- Utilize local or geo-targeted media in hot markets that have a high percentage of overweight consumers

**Budget:** \$555.2M (+12%)

**Timing:** Q2-Q3

**Media Mix:** Print: 47%; Radio/Digital: 53%

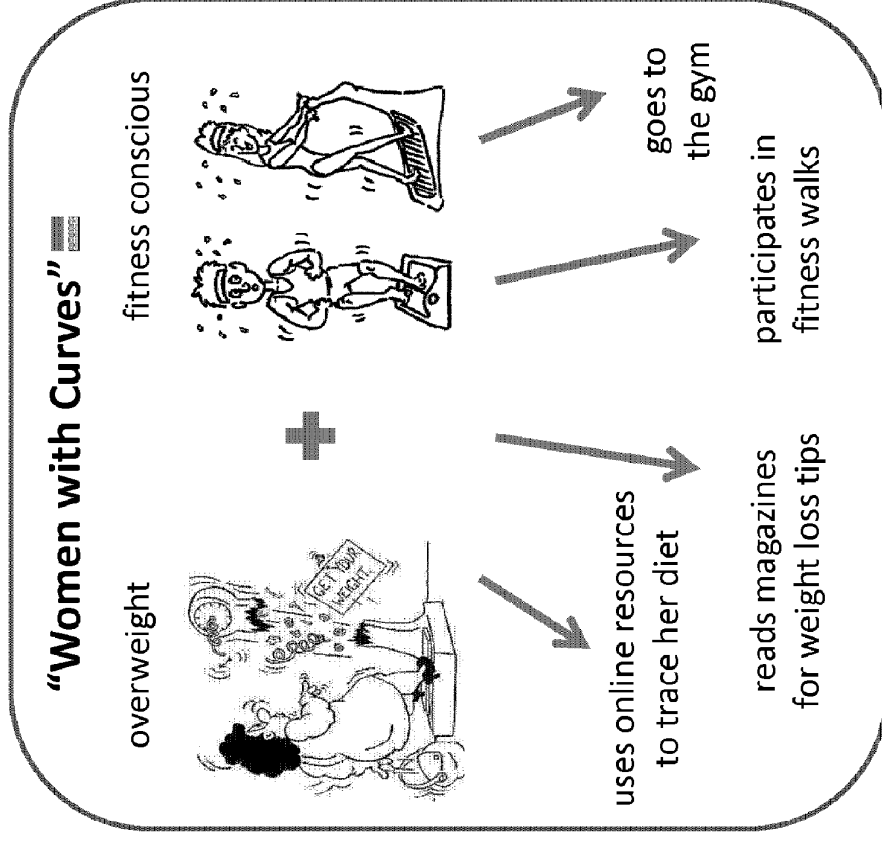




## 2008/2009 Programs targeted “Women with Curves”

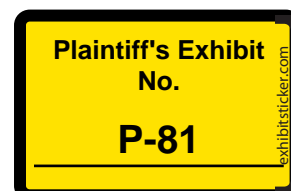
Historic target exhibited distinct behaviors that allowed JOHNSON’S® to reach her easily

- Print in Weight Watchers Magazine
  - Print out-performed norms for Weight Watchers magazine
  - Advertorials explained alternate usages
- Digital on diet sites
  - Digital banners slightly exceeded benchmarks with a .15% CTR
  - Hub on WeightWatchers.com to increase relevance of messaging vs. brand page, resulted in about 24,000 visits
- Sampling at gyms and walking events





# **EXHIBIT 39**




Definition: *License* - to permit, authorize, allow, certify.....

*You want to drive?* – You need to learn the rules and obtain a license.

*You want to fish?* – You need to learn the rules and obtain a license.

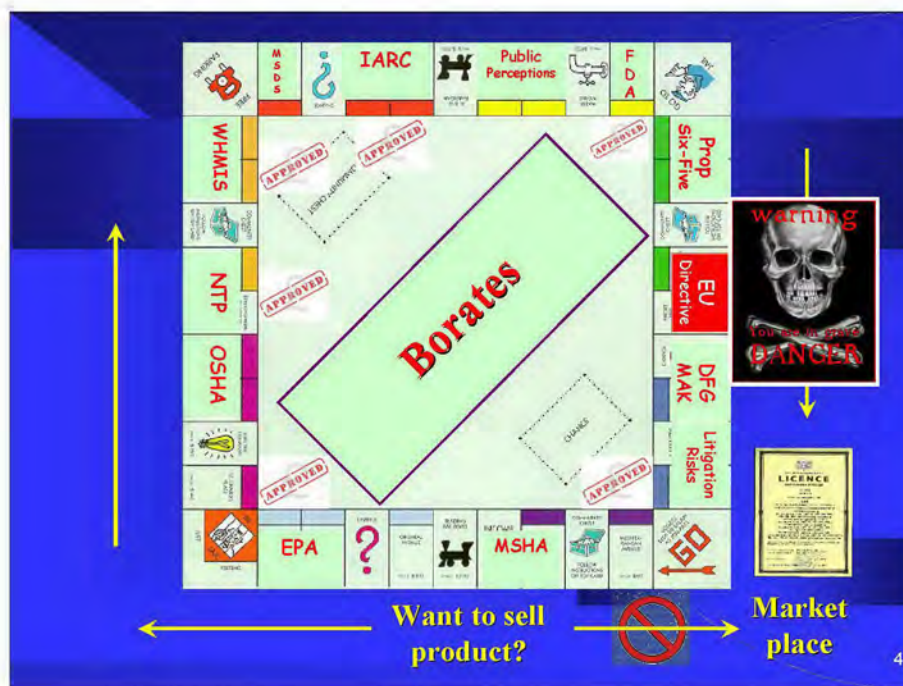
*You want to get married?* - You need to learn the rules (???) and obtain a license.

*You want to market a product?* – You need to learn the rules; and while you do not obtain an official marketplace license, a change in the rules can have a material effect on your ability to market your product.

 2



3









## What do we need to do to protect our license to market?

- Retain internal regulatory expert(s)
- Closely (and regularly) monitor regulatory and agency activities
- Utilize Internet tools e.g., "Google News Alerts"
- Establish and maintain ties with outside resources e.g., expert legal counsel, "watchdog" services (Center for Regulatory Effectiveness), medical experts with knowledge of your product, legislators, policy makers



6

# **EXHIBIT 40**



**Litigation Issues**  
**- February 26, 2002 -**

Redacted

Redacted

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Redacted

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1

Protected Document – Subject to Protective Order

Plaintiff's Exhibit  
No.

**P-26**

exhibitstick.com

LUZ013094

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## Specific Litigation Issues & Problems

Redacted

Redacted

• **NTP Carcinogenic Listing.** Listing of “talc not containing asbestos fibers” could be potentially devastating from a product liability perspective. [*Plaintiffs attorney: “So Mr. Zazenski, please tell the Court when Luzenac first learned that talc was possibly associated with ovarian cancer?” “When did you first start warning consumers that this association was possible and under study”. “Did you not feel a moral and ethical obligation to inform women that the hygienic use of talc may increase their risk for ovarian cancer, or were the profits you were making from mining and selling this potentially dangerous, life-threatening product more important than protecting the health and welfare of the women and children in our society?” Etc. etc. etc.*]

# **EXHIBIT 41**

[FDA Home](#)<sup>3</sup> [Medical Devices](#)<sup>4</sup> [Databases](#)<sup>5</sup>

## CFR - Code of Federal Regulations Title 21

The information on this page is current as of April 1 2015.

For the most up-to-date version of CFR Title 21, go to the [Electronic Code of Federal Regulations \(eCFR\)](#).<sup>6</sup>

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[Code of Federal Regulations]  
[Title 21, Volume 7]  
[Revised as of April 1, 2015]  
[CITE: 21CFR740.1]

TITLE 21--FOOD AND DRUGS  
CHAPTER I--FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
SUBCHAPTER G--COSMETICS  
PART 740 -- COSMETIC PRODUCT WARNING STATEMENTS  
Subpart A--General

Sec. 740.1 Establishment of warning statements.

(a) The label of a cosmetic product shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product.

(b) The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to establish or amend, under subpart B of this part, a regulation prescribing a warning for a cosmetic. Any such petition shall include an adequate factual basis to support the petition, shall be in the form set forth in part 10 of this chapter, and will be published for comment if it contains reasonable grounds for the proposed regulation.

[40 FR 8917, Mar. 3, 1975, as amended at 42 FR 15676, Mar. 22, 1977]

Plaintiff's Exhibit  
No.

P-324

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SID=3ee286332416f26a91d9e6d786a604ab&mc=true&tpl=/ecfrbrowse/Title21/21tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?SID=3ee286332416f26a91d9e6d786a604ab&mc=true&tpl=/ecfrbrowse/Title21/21tab_02.tpl)
7. </scripts/cdrh/cfdocs/search/default.cfm?FAQ=true>

8. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/ucm135680.htm>

Page Last Updated: 08/21/2015

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U.S. Department of **Health & Human Services**

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8. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/ucm135680.htm>